INPLASY PROTOCOL

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None declared.

Unilateral curved percutaneous vertebroplasty for osteoporotic vertebral compression fractures: A protocol for systematic review and meta-analysis

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Review question / Objective: **P: Osteoporotic vertebral compression fractures (OVCFs) I: Unilateral curved percutaneous vertebroplasty (UC-PVP) C: Unilateral or bilatera percutaneous vertebroplasty (U-PVP OR B-PVP) O: (1)surgery time, (2)visual analog scale (VAS) scores, (3)Oswestry Disability Index (ODI) scores, (4)X-ray frequency, (5)bone cement injection volume, (6)bone cement leakage rate, (7)ideal distribution ratio of bone cement S: Randomized controlled trials (RCTs).**
Condition being studied: **Unilateral curved percutaneous vertebroplasty (UC-PVP) is a new type of modified operation for osteoporotic vertebral compression fractures (OVCFs), which has been reported increasingly in recent years. However its security and effectiveness still lack of high-quality medical evidence. In this study, we will perform a systematic review of previously published randomized controlled trials (RCTs) to evaluate the efficacy and safety of UC-PVP for OVCFs.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 April 2021 and was last updated on 01 April 2021 (registration number INPLASY202140001).

INTRODUCTION

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METHODS

Search strategy: All potential RCTs on UC-PVP for OVCFs will be searched from the following electronic databases: PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure, Chinese Science and Technology Periodical Database, Wanfang database and Chinese Biomedical Literature Database.

Participant or population: The patients of osteoporotic vertebral compression fractures.

Intervention: The experimental group is treated with unilateral curved percutaneous vertebroplasty (UC-PVP).

Comparator: The control group is treated with unilateral percutaneous vertebroplasty (U-PVP) or bilatera percutaneous vertebroplasty (B-PVP).

Study designs to be included: Randomized controlled trials (RCTs) will be included in this systematic review regardless of publication status and language.

Eligibility criteria: We included trials that enrolled adults with a diagnosis of osteoporotic vertebral compression fracture/s of any duration. The diagnosis of osteoporosis could have been based upon bone mineral densitometry or explicit clinical diagnostic criteria as defined by the studies.

Information sources: All potential RCTs on UC-PVP for OVCFs will be searched from the following electronic databases: PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure, Chinese Science and Technology Periodical Database, Wanfang database and Chinese Biomedical Literature Database. We will search all electronic databases from their initiation to the April 1, 2021 in spite of language and publication date. To avoid missing potential trials, we will also retrieve conference papers, dissertations, ongoing studies, and reference list of all related reviews.

Main outcome(s): Primary outcomes : (1)surgery time (2)visual analog scale (VAS) scores (3)Oswestry Disability Index (ODI) scores (4)X-ray frequency; Secondary outcomes:(1)bone cement injection volume (2)bone cement leakage rate (3)ideal distribution ratio of bone cement.

Quality assessment / Risk of bias analysis: Two contributors will perform quality assessments and review the risk of bias using the Cochrane Collaboration's risk-of-bias assessment method (v6). This scale includes 7 risk of bias items, and each will be described as low, unclear, or high risk. Data will be presented in the risk of bias graph. Discrepancies will be resolved or as required, by a third reviewer.

Strategy of data synthesis: We will employ RevMan 5.3 (Cochrane Community, London, UK) software to synthesize and analyze the data, and to perform a meta-analysis if possible. If acceptable heterogeneity is examined among included trials, we will conduct a meta-analysis in accordance with the few variations in study and patient characteristics, and few differences in treatments, controls, and outcomes. If considerable heterogeneity is identified, we will carry out subgroup analysis and sensitivity analysis to find out any possible sources of obvious heterogeneity. If it is impossible to undertake a meta-analysis, we will report study results as a narrative summary.

Subgroup analysis: We will observe the source of considerable heterogeneity by subgroup analysis based on variations in study and patient characteristics, study quality, different interventions, comparators, and outcomes.

Sensitivity analysis: We will perform sensitivity analysis to test the robustness and satiability of conclusions by removing low quality trials, and trials with small sample size.

Country(ies) involved: China.

Keywords: Osteoporotic Vertebral Compression Fractures; Unilateral Curved Percutaneous Vertebroplasty; Meta-Analysis; Protocol.

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